Guidance for Industry, FDA Staff, Third-Party and Hospital Reprocessors

Frequently-Asked-Questions about the Reprocessing and Reuse of Single-Use Devices by Third-Party and Hospital Reprocessors; Three Additional Questions

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This document supersedes *Frequently-Asked-Questions about the Reprocessing and Reuse of Single-Use Devices by Third Party and Hospital Reprocessors; Two Additional Questions; Final Guidance for Industry and FDA Staff,* December 11, 2002

For questions regarding the use or interpretation of this guidance, contact Lily Ng at 301-796-5692 or by email to lxn@cdrh.fda.gov.

C·D·R·H
Center for Devices and Radiological Health

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

Outreach and Public Participation Branch
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Office of Health and Industry Programs

Preface

Public Comment

Written comments and suggestions may be submitted at any time for Agency consideration to Dockets Management Branch, Division of Management Systems and Policy, Office of Human Resources and Management Services, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD, 20852. When submitting comments, please refer to the exact title of this guidance document. Comments may not be acted upon by the Agency until the document is next revised or updated.

Additional Copies

Additional copies are available from the Internet at http://www.fda.gov/cdrh/ohip/guidance/1427.pdf. You may also send an e-mail request to dsmica@fda.hhs.gov to receive an electronic copy of the guidance or send a fax request to 301-847-8149 to receive a hard copy. Please use the document number (1427) to identify the guidance you are requesting.

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This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

Introduction

This document is intended to provide guidance. It represents the Agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind the Food and Drug Administration (FDA) or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

Background

On August 14, 2000, the Food and Drug Administration released a document entitled "Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals" to provide guidance to third-party and hospitals reprocessors about their responsibilities as manufacturers engaged in reprocessing devices labeled for single use under the Federal Food, Drug, and Cosmetic Act (the Act), as amended by the Safe Medical Devices Act of 1990, the

Medical Device Amendments of 1992, and the Food and Drug Modernization Act of 1997. Third-party and hospital reprocessors of single- use devices (SUDs) are subject to all the regulatory requirements currently applicable to original equipment manufacturers, including premarket submission requirements (Section 513 and 515 of the Act; 21 *Code of Federal Regulations* Parts 807 and 814).

Since its release on August 14, 2000, the agency has received numerous questions about the enforcement priorities guidance. The following questions and answers are meant as clarification of the original document. This guidance will be updated as the need arises.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

The Least Burdensome Approach

We believe we should consider the least burdensome approach in all areas of medical device regulation. This guidance reflects our careful review of the relevant scientific and legal requirements and what we believe is the least burdensome way for you to comply with those requirements. However, if you believe that an alternative approach would be less burdensome, please contact us so we can consider your point of view. You may send your written comments to the contact person listed in the preface to this guidance or to the CDRH Ombudsman. Comprehensive information on CDRH's Ombudsman, including ways to contact him, can be found on the Internet at http://www.fda.gov/cdrh/resolvingdisputes/ombudsman.html.

Questions related to REGISTRATION AND DEVICE LISTING

Question*: My establishment is registered as a manufacturer of medical devices, some of which are labeled for single use. We also reprocess for reuse some of the single-use devices that we manufacture. Do we have to add the establishment operation type of "Reprocessor of Single-Use Devices" to our existing registration information?*

Answer: Yes, your establishment needs to be registered for all of the operations that are being performed at the same location.

Question: *My establishment is registered as a manufacturer of medical devices, some of which are labeled for single use. We also reprocess for reuse some of the single-use devices that we manufacture. Do we have to update our existing device listing information?*

Answer: Yes, your establishment needs to have all of the operations that are being performed on a particular device listed with FDA.

Question related to HOSPITAL AND THIRD PARTY REPROCESSORS

Question: *Must all hospitals that use reprocessed devices intended for single use comply with the FDA requirements applicable to medical device manufacturers?*

Answer: No. Only those hospitals that actually reprocess medical devices labeled for single use must comply with FDA's medical device requirements applicable to manufacturers. FDA's regulatory requirements do not apply to hospitals that use a third party reprocessor to reprocess SUDs for reuse.